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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC Plaintiffs, v. SANDOZ INC. Defendant.	Case No. 3:18-cv-14895-BRM-DEA ***Jury Trial Demanded*** (Filed Electronically)

DEFENDANT SANDOZ INC.'S ANSWER AND DEFENSES TO
FIRST AMENDED COMPLAINT AND COUNTERCLAIMS

Defendant Sandoz Inc. ("Sandoz") hereby files its Answer, Defenses, and Counterclaims in response to the First Amended Complaint of Par Pharmaceutical, Inc. ("Par Pharmaceutical"), Par Sterile Products, LLC ("Par Sterile Products"), and Endo Par Innovation Company, LLC ("EPIC") (collectively "Par" or "Plaintiffs").

PARTIES

1. Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

RESPONSE:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of any and all allegations in Paragraph 1 and on that basis denies any and all of these allegations.

2. Plaintiff Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

RESPONSE:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of any and all allegations in Paragraph 2 and on that basis denies any and all of these allegations.

3. Plaintiff Endo Par Innovation Company ("EPIC") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

RESPONSE:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of any and all allegations in Paragraph 3 and on that basis denies any and all of these allegations.

4. Upon information and belief, Defendant Sandoz Inc. ("Sandoz") is a corporation organized and existing under the law of Colorado, having its corporate offices and principal place of business at 100 College Road West, Princeton, New Jersey 08540. Sandoz is a pharmaceutical company that markets pharmaceutical products in the United States.

RESPONSE:

Sandoz admits that it is a corporation organized and existing under the laws of Colorado and maintains a place of business at 100 College Road West, Princeton, New Jersey 08540. Sandoz further admits that it markets pharmaceutical products, including in the United States. Sandoz denies the remaining allegations of Paragraph 4.

NATURE OF ACTION

5. This is an action for infringement of United States Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent"), 9,744,209 ("the '209 Patent"), 9,744,239 ("the '239 Patent"), 9,750,785 ("the '785 Patent"), and 9,937,223 ("the '223 Patent") (collectively, "the Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

RESPONSE:

Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Plaintiffs' First Amended Complaint purports to state an action that arises under the Patent Laws of the United States and the Declaratory Judgment Act. Sandoz further admits that the action purports to concern U.S. Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent"), 9,744,209 ("the '209 Patent"), 9,744,239 ("the '239 Patent"), 9,750,785 ("the '785 Patent"), and 9,937,223 ("the '223 Patent") (collectively, "the Patents-in-Suit"). Sandoz denies the remaining allegations of Paragraph 5.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement).

RESPONSE:

Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that this Court has subject matter jurisdiction over Plaintiffs' alleged infringement claims under 35 U.S.C. § 271(e)(2)(A) pursuant to 28 U.S.C. §§ 1331, 1338(a). Sandoz denies the remaining allegations of Paragraph 6.

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) because, *inter alia*, Sandoz has its principal place of business in New Jersey and maintains laboratories and facilities in New Jersey, and thus resides in this district.

RESPONSE:

Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only, and reserves the right to contest venue in any other case. Sandoz admits that it maintains a place of business at 100 College Road West, Princeton, New Jersey 08540. Sandoz denies the remaining allegations of Paragraph 7.

8. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz has its principal place of business in New Jersey and maintains laboratories and facilities in New Jersey, and thus resides in this district.

RESPONSE:

Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case. Sandoz admits that it maintains a place of business at 100 College Road West, Princeton, New Jersey 08540. Sandoz denies the remaining allegations of Paragraph 8.

THE DRUG APPROVAL PROCESS

9. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration ("FDA"), typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

RESPONSE:

Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, 21 U.S.C. § 355 speaks for itself. Sandoz denies the remainder of the allegations of Paragraph 9.

10. Alternatively, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "referenced listed drug" or "branded drug").

RESPONSE:

Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, 21 U.S.C. § 355(j) speaks for itself. Sandoz denies the remainder of the allegations of Paragraph 10.

11. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). *See also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

RESPONSE:

Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.94(a)(12) speak for themselves. Sandoz denies the remainder of the allegations of Paragraph 11.

12. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owner of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. *See* 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

RESPONSE:

Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 speak for themselves. Sandoz denies the remainder of the allegations of Paragraph 12.

13. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to the innovator companies because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to an infringing product without first providing an opportunity for the infringement case to be resolved. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. 355(j)(5)(B)(iii).

RESPONSE:

Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, 21 U.S.C. § 355(j)(5)(B)(iii) and 21 C.F.R. § 314.107(b)(3) speak for themselves. Sandoz denies the remainder of the allegations of Paragraph 13.

FACTUAL BACKGROUND

The Patents-in-Suit

14. On June 28, 2016, the United States Patent and Trademark Office ("PTO") duly and legally issued the '478 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '478 Patent is attached as Exhibit A. Par Pharmaceutical owns the '478 Patent.

RESPONSE:

Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Exhibit A of the First Amended Complaint purports to be a copy of the '478 patent and that the face of Exhibit A states that the '478 patent purports to have been issued on June 28, 2016, and it lists Par Pharmaceutical as the purported assignee. Sandoz admits that on its face, the '478 patent is titled "Vasopressin Formulations for Use in Treatment of Hypotension." Sandoz denies that the '478 patent was "duly and legally issued" as

well as any suggestion that the '478 patent is valid and enforceable. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 14, and therefore denies them.

15. On June 27, 2017, the PTO duly and legally issued the '526 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '526 Patent is attached as Exhibit B. Par Pharmaceutical owns the '526 Patent.

RESPONSE:

Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Exhibit B of the First Amended Complaint purports to be a copy of the '526 patent and that the face of Exhibit B states that the '526 patent purports to have been issued on June 27, 2017, and it lists Par Pharmaceutical as the purported assignee. Sandoz admits that on its face, the '526 patent is titled "Vasopressin Formulations for Use in Treatment of Hypotension." Sandoz denies that the '526 patent was "duly and legally issued" as well as any suggestion that the '526 patent is valid and enforceable. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 15, and therefore denies them.

16. On August 29, 2017, the PTO duly and legally issued the '209 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '209 Patent is attached as Exhibit C. Par Pharmaceutical owns the '209 Patent.

RESPONSE:

Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Exhibit C of the First Amended Complaint purports to be a copy of the '209 patent and that the face of Exhibit C states that the '209 patent purports to have been issued on August 29, 2017, and it lists Par Pharmaceutical as the purported assignee. Sandoz admits that on its face, the '209 patent is titled "Vasopressin Formulations for Use in

Treatment of Hypotension." Sandoz denies that the '209 patent was "duly and legally issued" as well as any suggestion that the '209 patent is valid and enforceable. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 16, and therefore denies them.

17. On August 29, 2017, the PTO duly and legally issued the '239 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '239 Patent is attached as Exhibit D. Par Pharmaceutical owns the '239 Patent.

RESPONSE:

Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Exhibit D of the First Amended Complaint purports to be a copy of the '239 patent and that the face of Exhibit D states that the '239 patent purports to have been issued on August 29, 2017, and it lists Par Pharmaceutical as the purported assignee. Sandoz admits that on its face, the '239 patent is titled "Vasopressin Formulations for Use in Treatment of Hypotension." Sandoz denies that the '239 patent was "duly and legally issued" as well as any suggestion that the '239 patent is valid and enforceable. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 17, and therefore denies them.

18. On September 5, 2017, the PTO duly and legally issued the '785 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '785 Patent is attached as Exhibit E. Par Pharmaceutical owns the '785 Patent.

RESPONSE:

Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Exhibit E of the First Amended Complaint purports to be a copy of the '785 patent and that the face of Exhibit E states that the '785 patent purports to have been issued on September 5, 2017, and it lists Par Pharmaceutical as the purported assignee.

Sandoz admits that on its face, the '785 patent is titled "Vasopressin Formulations for Use in Treatment of Hypotension." Sandoz denies that the '785 patent was "duly and legally issued" as well as any suggestion that the '785 patent is valid and enforceable. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 18, and therefore denies them.

19. On April 10, 2018, the PTO duly and legally issued the '223 Patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '223 Patent is attached as Exhibit F. Par Pharmaceutical owns the '223 Patent.

RESPONSE:

Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Exhibit F of the First Amended Complaint purports to be a copy of the '223 patent and that the face of Exhibit F states that the '223 patent purports to have been issued on April 10, 2018, and it lists Par Pharmaceutical as the purported assignee. Sandoz admits that on its face, the '223 patent is titled "Vasopressin Formulations for Use in Treatment of Hypotension." Sandoz denies that the '223 patent was "duly and legally issued" as well as any suggestion that the '223 patent is valid and enforceable. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 19, and therefore denies them.

20. EPIC is the exclusive licensee of the Patents-in-Suit.

RESPONSE:

Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 20, and therefore denies them.

VASOSTRICT®

21. Vasopressin, the active ingredient in VASOSTRICT® (described below), is a polypeptide hormone that causes contraction of vascular and other smooth muscle cells. VASOSTRICT® is a lifesaving drug often used when the blood pressure of a critical care patient drops precipitously.

RESPONSE:

Sandoz admits that the electronic version of the FDA's publication Approved Drug Products and Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") identifies New Drug Application ("NDA") No. 204485 as purportedly for a solution containing vasopressin as the "Active Ingredient," and identifies Vasostrict® as the "Proprietary Name" for this product. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 21, and therefore denies them.

22. On September 25, 2012, JHP Pharmaceuticals ("JHP") submitted NDA No. 204485, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), seeking FDA approval for a vasopressin injection product to increase blood pressure in adults with vasodilatory shock. On April 17, 2014, the FDA approved NDA 204485 as the first FDA-approved vasopressin injection product for use in a clinical setting in the United States.

RESPONSE:

Sandoz admits that the electronic version of the Orange Book indicates that the FDA approved NDA No. 204485 on April 17, 2014. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 22, and therefore denies them.

23. On February 20, 2014, Par Pharmaceutical Companies, Inc. acquired JHP Pharmaceuticals, LLC. On February 26, 2014, JHP Pharmaceuticals, LLC changed its name to Par Sterile Products, LLC.

RESPONSE:

Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 23, and therefore denies them.

24. Par Sterile Products submitted supplemental NDAs including supplemental NDA Nos. 204485/S-003 and 204485/S-004 for the current formulations of VASOSTRICT®—20 units/mL in 1mL vials and 200 units/10mL in 10mL multi-dose vials. On March 18, 2016, the FDA approved NDA No. 204485/S-003 for the 20 units/mL in 1mL vial formulation of VASOSTRICT®. On December 17, 2016, the FDA approved NDA No. 204485/S-004 for the 200 units/10mL in 10mL vial formulation of VASOSTRICT®.

RESPONSE:

Sandoz admits that the FDA website indicates that the FDA approved NDA No. 204485/S-003 on March 18, 2016, and NDA No. 204485/S-004 on December 17, 2016. Sandoz further admits that the electronic version of the Orange Book indicates that the FDA approved NDA No. 204485 for the 200 units/10mL in 10mL vial formulation of Vasostrict® on December 17, 2016. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 24, and therefore denies them.

25. Par Sterile Products is the holder of NDA 204485, including all supplements thereto, for VASOSTRICT®.

RESPONSE:

Sandoz admits that the electronic version of the Orange Book identifies Par Sterile Products as the purported applicant holder for NDA No. 204485 for Vasostrict®. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 25, and therefore denies them.

26. Par timely submitted information regarding the Patents-in-Suit for listing in the Orange Book with respect to VASOSTRICT®, pursuant to 21 U.S.C. § 355(b)(1) and (c)(2). The FDA thereafter listed the Patents-in-Suit in the Orange Book, pursuant to 21 C.F.R. § 314.53(e).

RESPONSE:

Paragraph 26 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that the Patents-in-Suit are listed in the Orange Book in connection with Vasostrict® (NDA No. 204485). Sandoz lacks knowledge or information

sufficient to form a belief about the truth of the remaining allegations of Paragraph 26, and therefore denies them.

27. VASOSTRICT® is FDA-approved as indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Par markets and sells its VASOSTRICT® products to hospitals, both directly and via group purchasing organizations and wholesalers. VASOSTRICT® has enjoyed tremendous commercial success, with 2017 annual sales of $400 million.

RESPONSE:

Sandoz admits that the electronic version of the Orange Book indicates that the FDA approved Vasostrict® on April 17, 2014. Sandoz further admits that the Prescribing Information for Vasostrict® states that "Vasostrict® is indicated to increase blood pressure in adults with vasodilatory shock (e.g., postcardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines." Sandoz lacks sufficient knowledge and information to form a belief as to the remaining allegations of Paragraph 27 and therefore denies the same.

Sandoz's Vasopressin Injection Product

28. Upon information and belief, on or before August 31, 2018, Sandoz submitted ANDA No. 212069 ("Sandoz Multi-Dose ANDA") pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic "Vasopressin Injection USP, 200 units/10mL (20 units/mL) multiple-dose vials," referencing Par's VASOSTRICT® products as the reference listed drug ("Proposed Multi-Dose Vial Product"). The dosage form of the Proposed Multi-Dose Vial Product is a multiple dose injection solution.

RESPONSE:

Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 212069 to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Vasopressin Injection USP, 200 units/10mL (20 units/mL), multiple-dose vials and that the ANDA references Vasostrict®. Sandoz denies the remaining allegations of Paragraph 28.

29. On or about August 31, 2018, Sandoz sent Par Pharmaceutical, Par Sterile Products, and EPIC a notice stating that Sandoz had submitted the Sandoz Multi-Dose ANDA seeking approval to manufacture, use, or sell the Proposed Multi-Dose Vial Product prior to the expiration of the Patents-in-Suit (the "Multi-Dose Paragraph IV Notice").

RESPONSE:

Paragraph 29 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it sent a letter dated August 31, 2018, ("Multi-Dose Paragraph IV Notice") to Par Pharmaceutical, Par Sterile Products, and EPIC. Sandoz admits that the Multi-Dose Paragraph IV Notice provided Par Pharmaceutical, Par Sterile Products, and EPIC with written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Sandoz submitted ANDA No. 212069 to the FDA seeking approval to manufacture, use, or sell Sandoz's Vasopressin Injection USP, 200 units/10mL (20 units/mL), multiple-dose vials prior to the expiration of the Patents-in-Suit. Sandoz denies the remaining allegations of Paragraph 29.

30. The Multi-Dose Paragraph IV Notice advised that the Sandoz Multi-Dose ANDA includes Paragraph IV Certifications stating that it is Sandoz's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed Multi-Dose Vial Product.

RESPONSE:

Paragraph 30 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Multi-Dose Paragraph IV Notice provided Par Pharmaceutical, Par Sterile Products, and EPIC with written notification that Sandoz submitted ANDA No. 212069 with Paragraph IV Certifications that the '478, '526, '209, '239, '785, and '223 Patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Sandoz's Vasopressin Injection USP, 200 units/10mL (20 units/mL), multiple-dose vials. Sandoz denies the remaining allegations of Paragraph 30.

31. Upon information and belief, on or before October 17, 2018, Sandoz submitted ANDA No. 212068 ("Sandoz Single-Dose ANDA") pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic "Vasopressin Injection USP, 20 units/1mL, Single-Dose Vials," referencing Par's

VASOSTRICT® products as the reference listed drug (the "Proposed Single-Dose Vial Product"). The dosage form of the Proposed Single-Dose Vial Product is a single dose injection solution.

RESPONSE:

Paragraph 31 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted ANDA No. 212068 to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Vasopressin Injection USP, 20 units/1mL, single-dose vials and that the ANDA references Vasostrict®. Sandoz denies the remaining allegations of Paragraph 31.

32. On or about October 17, 2018, Sandoz sent Par Pharmaceutical, Par Sterile Products, and EPIC a notice stating that Sandoz had submitted the Sandoz Single-Dose ANDA seeking approval to manufacture, use, or sell the Proposed Single-Dose Vial Product prior to the expiration of the Patents-in-Suit (the "Single-Dose Paragraph IV Notice").

RESPONSE:

Paragraph 32 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it sent a letter dated October 17, 2018, ("Single-Dose Paragraph IV Notice") to Par Pharmaceutical, Par Sterile Products, and EPIC. Sandoz admits that the Single-Dose Paragraph IV Notice provided Par Pharmaceutical, Par Sterile Products, and EPIC with written notification pursuant to 21 U.S.C. § 355(j)(2)(B) that Sandoz submitted ANDA No. 212068 to the FDA seeking approval to manufacture, use, or sell the Vasopressin Injection USP, 20 units/1mL, single-dose vials prior to the expiration of the Patents-in-Suit. Sandoz denies the remaining allegations of Paragraph 32.

33. The Single-Dose Paragraph IV Notice advised that the Sandoz Single-Dose ANDA includes Paragraph IV Certifications stating that it is Sandoz's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed Single-Dose Vial Product.

RESPONSE:

Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Single-Dose Paragraph IV Notice provided Par Pharmaceutical, Par Sterile Products, and EPIC with written notification that Sandoz submitted ANDA No. 212068 with Paragraph IV Certifications that the '478, '526, '209, '239, and '785 Patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Sandoz's Vasopressin Injection USP, 20 units/1mL, single-dose vials. Sandoz denies the remaining allegations of Paragraph 33.

COUNT I
ALLEGED INFRINGEMENT OF THE '239 PATENT (SANDOZ ANDA 212069)

34. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

35. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '239 Patent, constitutes infringement of the '239 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 35 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 35.

36. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '239 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '239 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 36 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 36.

37. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '239 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) providing a pharmaceutical composition for intravenous administration consisting of, in a unit dosage form:
>
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
>
> ii) optionally chlorobutanol;
>
> iii) acetic acid, acetate, or a combination thereof;
>
> iv) 0-2% vasopressin degradation products; and
>
> v) water;
>
> b) diluting the unit dosage form in a diluent to provide a concentration from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and
>
> c) administering the diluted unit dosage form to the human by intravenous administration; wherein:
>
> the unit dosage form has a pH of 3.5 to 4.1;
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive.

RESPONSE:

Paragraph 37 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 37.

38. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 38 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 38.

39. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '239 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 39 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 39.

40. Upon information and belief, Sandoz was aware of the existence of the '239 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '239 Patent.

RESPONSE:

Paragraph 40 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '239 patent on the date it submitted ANDA No. 212069. All remaining allegations of paragraph 40 are denied.

41. Sandoz's infringement of the '239 Patent is willful.

RESPONSE:

Paragraph 41 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212069, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 41.

COUNT II
ALLEGED INFRINGEMENT OF THE '223 PATENT (SANDOZ ANDA 212069)

42. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

43. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '223 Patent, constitutes infringement of the '223 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 43 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 43.

44. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '223 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '223 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 44 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 44.

45. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '223 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) providing a pharmaceutical composition for intravenous administration comprising:
>
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof;
>
> ii) acetate buffer; and
>
> iii) water; wherein the pharmaceutical composition has a pH from about 3.7 to about 3.8;
>
> wherein the pharmaceutical composition is provided in a container;
>
> b) puncturing a dispensing region of the container a first time and drawing from the container a portion of the pharmaceutical composition;
>
> c) intravenously administering the portion of the pharmaceutical composition to the human; wherein:
>
> the human is hypotensive;

d) puncturing the dispensing region of the container a second time and drawing from the container a second portion of the pharmaceutical composition; wherein:

the second time that the dispensing region of the container is punctured occurs at least 48 hours after the first time that the dispensing region of the container is punctured;

e) intravenously administering the second portion of the pharmaceutical composition to the human; wherein:

the administration of the second portion of the pharmaceutical composition provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically acceptable salt thereof per minute.

RESPONSE:

Paragraph 45 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 45.

46. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 46 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 46.

47. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the ’223 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 47 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 47.

48. Upon information and belief, Sandoz was aware of the existence of the ’223 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the ’223 Patent.

RESPONSE:

Paragraph 48 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '223 patent on the date it submitted ANDA No. 212069. All remaining allegations of paragraph 48 are denied.

49. Sandoz's infringement of the '223 Patent is willful.

RESPONSE:

Paragraph 49 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212069, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 49.

COUNT III
ALLEGED INFRINGEMENT OF THE '478 PATENT (SANDOZ ANDA 212069)

50. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

51. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '478 Patent, constitutes infringement of the '478 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 51 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 51.

52. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '478 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '478 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 52 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 52.

53. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '478 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human in a unit dosage form, wherein the unit dosage form consists essentially of:
>
> a) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
>
> b) 10 mM acetate buffer; and
>
> c) water; wherein:
>
> the unit dosage form has a pH of 3.8;
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive.

RESPONSE:

Paragraph 53 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 53.

54. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 54 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 54.

55. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '478 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 55 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 55.

56. Upon information and belief, Sandoz was aware of the existence of the '478 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '478 Patent.

RESPONSE:

Paragraph 56 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '478 patent on the date it submitted ANDA No. 212069. All remaining allegations of paragraph 56 are denied.

57. Sandoz's infringement of the '478 Patent is willful.

RESPONSE:

Paragraph 57 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212069, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 57.

COUNT IV
ALLEGED INFRINGEMENT OF THE '526 PATENT (SANDOZ ANDA 212069)

58. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

59. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '526 Patent, constitutes infringement of the '526 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 59 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 59.

60. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '526 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '526 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 60 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 60.

61. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '526 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) providing a pharmaceutical composition for intravenous administration comprising:
>
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
>
> ii) acetic acid; and
>
> iii) water; wherein:
>
> the pharmaceutical composition has a pH of 3.8;
>
> b) storing the pharmaceutical composition at 2-8° C. for at least 4 weeks; and
>
> c) intravenously administering the pharmaceutical composition to the human; wherein:
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; wherein:
>
> the human is hypotensive; wherein:
>
> the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

RESPONSE:

Paragraph 61 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 61.

62. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 62 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 62.

63. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the ’526 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 63 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 63.

64. Upon information and belief, Sandoz was aware of the existence of the ’526 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the ’526 Patent.

RESPONSE:

Paragraph 64 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the ’526 patent on the date it submitted ANDA No. 212069. All remaining allegations of paragraph 64 are denied.

65. Sandoz’s infringement of the ’526 Patent is willful.

RESPONSE:

Paragraph 65 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No.

212069, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 65.

COUNT V
ALLEGED INFRINGEMENT OF THE '785 PATENT (SANDOZ ANDA 212069)

66. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

67. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '785 Patent, constitutes infringement of the '785 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 67 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 67.

68. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '785 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '785 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 68 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 68.

69. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '785 Patent, which recites as follows:

Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

RESPONSE:

Paragraph 69 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 69.

70. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 70 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 70.

71. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the ’785 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 71 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 71.

72. Upon information and belief, Sandoz was aware of the existence of the ’785 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the ’785 Patent.

RESPONSE:

Paragraph 72 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the ’785 patent on the date it submitted ANDA No. 212069. All remaining allegations of paragraph 72 are denied.

73. Sandoz’s infringement of the ’785 Patent is willful.

RESPONSE:

Paragraph 73 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212069, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 73.

COUNT VI
ALLEGED INFRINGEMENT OF THE '209 PATENT (SANDOZ ANDA 212069)

74. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

75. Sandoz's submission of the Sandoz Multi-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Multi-Dose Vial Product prior to the expiration of the '209 Patent, constitutes infringement of the '209 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 75 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 75.

76. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product before expiration of the '209 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '209 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 76 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 76.

77. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product would lead to such infringement of at least claim 1 of the '209 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:
>
> the unit dosage form has a pH of 3.7-3.9;
>
> the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive.

RESPONSE:

Paragraph 77 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 77.

78. If the Proposed Multi-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 78 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 78.

79. Any launch by Sandoz of its Proposed Multi-Dose Vial Product before expiration of the '209 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 79 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 79.

80. Upon information and belief, Sandoz was aware of the existence of the '209 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Multi-Dose Vial Product will lead to infringement of the '209 Patent.

RESPONSE:

Paragraph 80 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '209 patent on the date it submitted ANDA No. 212069. All remaining allegations of Paragraph 80 are denied.

81. Sandoz's infringement of the '209 Patent is willful.

RESPONSE:

Paragraph 81 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212069, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 81.

COUNT VII
ALLEGED INFRINGEMENT OF THE '239 PATENT (SANDOZ ANDA 212068)

82. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

83. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '239 Patent, constitutes infringement of the '239 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 83 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 83.

84. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '239 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '239 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 84 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 84.

85. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '239 Patent, which recites as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:

a) providing a pharmaceutical composition for intravenous administration consisting of, in a unit dosage form:

i) from about 0.01mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;

ii) optionally chlorobutanol;

iii) acetic acid, acetate, or a combination thereof;

iv) 0-2% vasopressin degradation products; and

v) water;

b) diluting the unit dosage form in a diluent to provide a concentration from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and

c) administering the diluted unit dosage form to the human by intravenous administration; wherein:

the unit dosage form has a pH of 3.5 to 4.1;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive.

RESPONSE:

Paragraph 85 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 85.

86. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 86 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 86.

87. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the ’239 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 87 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 87.

88. Upon information and belief, Sandoz was aware of the existence of the ’239 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the ’239 Patent.

RESPONSE:

Paragraph 88 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the ’239 patent on the date it submitted ANDA No. 212068. All remaining allegations of Paragraph 88 are denied.

89. Sandoz’s infringement of the ’239 Patent is willful.

RESPONSE:

Paragraph 89 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212068, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp.*

v. Teva Pharms. USA, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 89.

COUNT VIII
ALLEGED INFRINGEMENT OF THE '223 PATENT (SANDOZ ANDA 212068)

90. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

91. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '223 Patent, constitutes infringement of the '223 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 91 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 91.

92. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '223 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '223 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 92 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 92.

93. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '223 Patent, which recites as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:

a) providing a pharmaceutical composition for intravenous administration comprising:

i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof;

ii) acetate buffer; and

iii) water; wherein the pharmaceutical composition has a pH from about 3.7 to about 3.8;

wherein the pharmaceutical composition is provided in a container;

b) puncturing a dispensing region of the container a first time and drawing from the container a portion of the pharmaceutical composition;

c) intravenously administering the portion of the pharmaceutical composition to the human; wherein:

the human is hypotensive;

d) puncturing the dispensing region of the container a second time and drawing from the container a second portion of the pharmaceutical composition; wherein:

the second time that the dispensing region of the container is punctured occurs at least 48 hours after the first time that the dispensing region of the container is punctured;

e) intravenously administering the second portion of the pharmaceutical composition to the human; wherein:

the administration of the second portion of the pharmaceutical composition provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 unites of vasopressin or the pharmaceutically acceptable salt thereof per minute.

RESPONSE:

Paragraph 93 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 93.

94. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 94 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 94.

95. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the ’223 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 95 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 95.

96. Upon information and belief, Sandoz was aware of the existence of the '223 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '223 Patent.

RESPONSE:

Paragraph 96 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '223 patent on the date it submitted ANDA No. 212068. All remaining allegations of Paragraph 96 are denied.

97. Sandoz's infringement of the '223 Patent is willful.

RESPONSE:

Paragraph 97 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212068, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 97.

COUNT IX
ALLEGED INFRINGEMENT OF THE '478 PATENT (SANDOZ ANDA 212068)

98. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

99. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '478 Patent, constitutes infringement of the '478 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 99 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 99.

100. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '478 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '478 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 100 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 100.

101. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '478 Patent, which recites as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human in a unit dosage form, wherein the unit dosage form consists essentially of:

a) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;

b) 10 mM acetate buffer; and

c) water; wherein:

the unit dosage form has a pH of 3.8;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive.

RESPONSE:

Paragraph 101 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 101.

102. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 102 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 102.

103. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '478 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 103 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 103.

104. Upon information and belief, Sandoz was aware of the existence of the '478 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '478 Patent.

RESPONSE:

Paragraph 104 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '478 patent on the date it submitted ANDA No. 212068. All remaining allegations of Paragraph 104 are denied.

105. Sandoz's infringement of the '478 Patent is willful.

RESPONSE:

Paragraph 105 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212068, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 105.

COUNT X
ALLEGED INFRINGEMENT OF THE '526 PATENT (SANDOZ ANDA 212068)

106. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

107. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '526 Patent, constitutes infringement of the '526 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 107 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 107.

108. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '526 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '526 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 108 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 108.

109. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '526 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
>
> a) providing a pharmaceutical composition for intravenous administration comprising:
>
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
>
> ii) acetic acid; and
>
> iii) water; wherein:
>
> the pharmaceutical composition has a pH of 3.8;

b) storing the pharmaceutical composition at 2-8° C. for at least 4 weeks; and

c) intravenously administering the pharmaceutical composition to the human; wherein:

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about

0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; wherein:

the human is hypotensive; wherein:

the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

RESPONSE:

Paragraph 109 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 109.

110. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 110 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 110.

111. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the ’526 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 111 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 111.

112. Upon information and belief, Sandoz was aware of the existence of the ’526 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the ’526 Patent.

RESPONSE:

Paragraph 112 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '526 patent on the date it submitted ANDA No. 212068. All remaining allegations of Paragraph 112 are denied.

113. Sandoz's infringement of the '526 Patent is willful.

RESPONSE:

Paragraph 113 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212068, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 113.

COUNT XI
ALLEGED INFRINGEMENT OF THE '785 PATENT (SANDOZ ANDA 212068)

114. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

115. Sandoz's submission of the Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '785 Patent, constitutes infringement of the '785 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 115 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 115.

116. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '785 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '785 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 116 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 116.

117. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '785 Patent, which recites as follows:

Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

RESPONSE:

Paragraph 117 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 117.

118. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 118 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 118.

119. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '785 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 119 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 119.

120. Upon information and belief, Sandoz was aware of the existence of the '785 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '785 Patent.

RESPONSE:

Paragraph 120 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '785 patent on the date it submitted ANDA No. 212068. All remaining allegations of Paragraph 120 are denied.

121. Sandoz's infringement of the '785 Patent is willful.

RESPONSE:

Paragraph 121 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212068, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 121.

COUNT XII
ALLEGED INFRINGEMENT OF THE '209 PATENT (SANDOZ ANDA 212068)

122. Par incorporates each of the preceding paragraphs as if fully set forth herein.

RESPONSE:

Sandoz repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

123. Sandoz's submission of Sandoz Single-Dose ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed Single-Dose Vial Product prior to the expiration of the '209 Patent, constitutes infringement of the '209 Patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE:

Paragraph 123 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 123.

124. Any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product before expiration of the '209 Patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '209 Patent under 35 U.S.C. §§ 271(a)-(c).

RESPONSE:

Paragraph 124 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 124.

125. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product would lead to such infringement of at least claim 1 of the '209 Patent, which recites as follows:

Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:

the unit dosage form has a pH of 3.7-3.9;

the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and the human is hypotensive.

RESPONSE:

Paragraph 125 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 125.

126. If the Proposed Single-Dose Vial Product is administered as intended, doctors, nurses, and/or other medical personnel would perform each and every step of the method of

treatment recited in claim 1. By virtue of its proposed product label and other conduct, Sandoz would actively and intentionally induce such infringement.

RESPONSE:

Paragraph 126 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 126.

127. Any launch by Sandoz of its Proposed Single-Dose Vial Product before expiration of the '209 Patent would cause Par to suffer immediate and irreparable harm.

RESPONSE:

Paragraph 127 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 127.

128. Upon information and belief, Sandoz was aware of the existence of the '209 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed Single-Dose Vial Product will lead to infringement of the '209 Patent.

RESPONSE:

Paragraph 128 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it was aware of the '209 patent on the date it submitted ANDA No. 212068. All remaining allegations of Paragraph 128 are denied.

129. Sandoz's infringement of the '209 Patent is willful.

RESPONSE:

Paragraph 129 contains legal conclusions for which no answer is required. To the extent an answer is required, the First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing act performed by Sandoz is the filing of ANDA No. 212068, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006). Sandoz denies the allegations of Paragraph 129.

RESPONSES TO PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. Sandoz further denies that Plaintiffs are entitled to any of the relief set forth in their "Prayer for Relief" or to any relief whatsoever.

JURY DEMAND

Sandoz demands trial by jury as to all issues so triable.

DEFENSES

Without any admission or implication as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Sandoz asserts the following defenses:

FIRST DEFENSE
(INVALIDITY OF THE PATENTS-IN-SUIT)

One or more claims of the '478, '526, '209, '239, '785, or '223 patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents. For example, without limitation, the '478, '526, '209, '239, '785, or '223 patents are invalid for the reasons set forth in Sandoz Inc.'s Detailed Statement of the Factual and Legal Bases for Its Opinion That U.S. Patent Nos. 9,375,478; 9,687,526; 9,744,209; 9,744,239; 9,750,785; and 9,937,223 Are Invalid, Unenforceable and/or Not Infringed by the Manufacture, Use, Importation, Sale or Offer for Sale of the Sandoz Product, which was served by Sandoz on Par Pharmaceutical, Par Sterile Products, and EPIC, sent August 31, 2018 ("MDV Detailed Statement"), and Sandoz Inc.'s Detailed

Statement of the Factual and Legal Bases for Its Opinion That U.S. Patent Nos. 9,375,478; 9,687,526; 9,744,209; 9,744,239; and 9,750,785 Are Invalid, Unenforceable and/or Not Infringed by the Manufacture, Use, Importation, Sale or Offer for Sale of the Sandoz Product, which was served by Sandoz on Par Pharmaceutical, Par Sterile Products, and EPIC, sent October 17, 2018 ("SDV Detailed Statement") (collectively, "Sandoz's Detailed Statements").

SECOND DEFENSE
(NON-INFRINGEMENT OF THE PATENTS-IN-SUIT)

The manufacture, use, sale, offer for sale, and/or importation of the products described in ANDA Nos. 212068 and 212069 does not and will not infringe, induce infringement of, or contribute to the infringement of any valid and/or enforceable claims of the '478, '526, '209, '239, '785, or '223 patents, either literally or by the doctrine of equivalents. For example, without limitation, the manufacture, use, sale, offer for sale, or importation of the products described in ANDA Nos. 212068 and 212069 has not infringed, does not infringe, and would not infringe any valid claim of the '478, '526, '209, '239, '785, or '223 patents for the reasons set forth in Sandoz's Detailed Statements.

THIRD DEFENSE
(FAILURE TO STATE A CLAIM FOR DIRECT INFRINGEMENT)

Plaintiffs have failed to state a claim upon which relief can be granted. The First Amended Complaint fails to allege that Sandoz would directly infringe any claim of the '478, '526, '209, '239, '785, or '223 patents under 35 U.S.C. § 271(e)(2) if Sandoz's Vasopressin Injection USP, 20 units/1mL, single-dose vials and Vasopressin Injection USP, 200 units/10mL (20 units/mL), multiple-dose vials are approved and marketed.

FOURTH DEFENSE
(FAILURE TO STATE A CLAIM FOR INDIRECT INFRINGEMENT)

Plaintiffs have failed to state a claim upon which relief can be granted with respect to purported indirect infringement. The First Amended Complaint contains only conclusory allegations that "Sandoz would actively and intentionally induce such infringement" for each of the Patents-in-Suit and that Sandoz's activities "would lead to direct infringement, contributory infringement, and/or active inducement of infringement . . . under 35 U.S.C. §§ 271(a)-(c)" for each patent. As such, Plaintiffs' First Amended Complaint fails to state a claim for either induced infringement or contributory infringement.

FIFTH DEFENSE
(FAILURE TO STATE A CLAIM FOR WILLFUL INFRINGEMENT)

The First Amended Complaint fails to state a claim for willful infringement because the only allegedly infringing acts performed by Sandoz are the filing of ANDA Nos. 212068 and 212069, which is insufficient as a matter of law to support a claim for willful infringement under 35 U.S.C. § 284. *Glaxo Group v. Apotex*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Celgene Corp. v. Teva Pharms. USA*, 412 F. Supp. 2d 439, 445 (D.N.J. 2006).

SIXTH DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION UNDER 35 U.S.C. § 271(a), (b), and (c))

The Court lacks subject lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and (c).

SEVENTH DEFENSE
(NOT AN EXCEPTIONAL CASE)

Sandoz's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

EIGHTH DEFENSE
(CHANGE OF VENUE FOR THE CONVENIENCE OF THE PARTIES)

For the convenience of the parties and witnesses, in the interest of justice, venue should be transferred under 28 U.S.C. § 1404 from this District to the District of Delaware where *Par Pharmaceutical, Inc. et al. v. Eagle Pharmaceuticals Inc.*, No. 1:18-cv-823 (D. Del.) is currently pending.

NINTH DEFENSE
(ADDITIONAL DEFENSES DISCOVERY MAY REVEAL)

Any additional defenses that discovery may reveal.

RESERVATION OF DEFENSES

Sandoz hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, Local Patent Rules and the U.S. Patent Law and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation, including unenforceability.

COUNTERCLAIMS OF SANDOZ INC.

Defendant/Counterclaim-Plaintiff Sandoz Inc. ("Sandoz") brings the following Counterclaims against Plaintiffs/Counterclaim-Defendants Par Pharmaceutical, Inc. ("Par Pharmaceutical"), Par Sterile Products, LLC ("Par Sterile Products"), and Endo Par Innovation Company, LLC ("EPIC") (collectively, "Par" or "Plaintiffs/Counterclaim-Defendants"). By pleading these counterclaims, Sandoz does not waive any defenses, including (but not limited to) its right to request change of venue under 28 U.S.C. § 1404.

NATURE OF THE ACTION

1. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* (including 35

U.S.C. § 271(e)(5)); and/or 21 U.S.C. § 355(j)(5)(C), based on an actual controversy between the parties to declare that Sandoz is free to continue to seek final approval of its Abbreviated New Drug Application ("ANDA") Nos. 212068 and 212069, and upon approval by the U.S. Food and Drug Administration ("FDA") to engage in commercial manufacture, importation, sale, and/or offer for sale of the products described in ANDA Nos. 212068 and 212069.

THE PARTIES

2. Defendant/Counterclaim-Plaintiff Sandoz is a corporation organized and existing under the laws of Colorado, with a place of business at 100 College Road West, Princeton, New Jersey 08540.

3. Plaintiff/Counterclaim-Defendant Par Pharmaceutical, Inc. ("Par Pharmaceutical") purports to be a corporation organized and existing under the laws of the State of New York, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Plaintiff/Counterclaim-Defendant Par Sterile Products, LLC ("Par Sterile Products") purports to be a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

5. Plaintiff/Counterclaim-Defendant Endo Par Innovation Company ("EPIC") purports to be a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

6. Par Pharmaceutical purports to be the lawful owner of U.S. Pat. No. 9,375,478 ("the '478 Patent"). The face of the '478 patent indicates that it is titled "Vasopressin Formulations for Use in Treatment of Hypotension," and it was issued by the U.S. Patent and Trademark Office on June 28, 2016.

7. Par Pharmaceutical purports to be the lawful owner of U.S. Pat. No. 9,687,526 ("the '526 Patent"). The face of the '526 patent indicates that it is titled "Vasopressin Formulations for Use in Treatment of Hypotension," and it was issued by the U.S. Patent and Trademark Office on June 27, 2017.

8. Par Pharmaceutical purports to be the lawful owner of U.S. Pat. No. 9,744,209 ("the '209 Patent"). The face of the '209 patent indicates that it is titled "Vasopressin Formulations for Use in Treatment of Hypotension," and it was issued by the U.S. Patent and Trademark Office on August 29, 2017.

9. Par Pharmaceutical purports to be the lawful owner of U.S. Pat. No. 9,744,239 ("the '239 Patent"). The face of the '239 patent indicates that it is titled "Vasopressin Formulations for Use in Treatment of Hypotension," and it was issued by the U.S. Patent and Trademark Office on August 29, 2017.

10. Par Pharmaceutical purports to be the lawful owner of U.S. Pat. No. 9,750,785 ("the '785 Patent"). The face of the '785 patent indicates that it is titled "Vasopressin Formulations for Use in Treatment of Hypotension," and it was issued by the U.S. Patent and Trademark Office on September 5, 2017.

11. Par Pharmaceutical purports to be the lawful owner of U.S. Pat. No. 9,937,223 ("the '223 Patent"). The face of the '223 patent indicates that it is titled "Vasopressin Formulations for Use in Treatment of Hypotension," and it was issued by the U.S. Patent and Trademark Office on April 10, 2018.

JURISDICTION AND VENUE

12. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

13. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331, 1337(a) and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

14. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because Plaintiffs/Counterclaim-Defendants have availed themselves of the rights and privileges and subjected themselves to the jurisdiction of this forum by suing Sandoz Inc. in this District, and/or because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

15. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400 and 21 U.S.C. § 355(j)(5)(C)(i)(II).

BACKGROUND

Plaintiffs/Counterclaim-Defendants' Suit

16. On October 11, 2018, Plaintiffs/Counterclaim-Defendants filed a Complaint in this Court seeking, among other things, a judgment that Sandoz has infringed the '478, '526, '209, '239, '785, and '223 patents (collectively, "the Patents-in-Suit"); and/or will actively induce infringement by others of the Patents-in-Suit by filing certifications for these patents pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) ("Paragraph IV Certification") in connection with Sandoz's ANDA No. 212069.

17. On November 8, 2018, Plaintiffs/Counterclaim-Defendants filed a First Amended Complaint in which Plaintiffs/Counterclaim-Defendants included additional allegations seeking, among other things, a judgment that Sandoz has infringed the Patents-in-Suit; and/or will

actively induce infringement by others of the Patents-in-Suit by filing Paragraph IV Certifications in connection with Sandoz's ANDA No. 212068.

18. An immediate and justiciable controversy exists between Sandoz, on the one hand, and Plaintiffs/Counterclaim-Defendants, on the other, regarding whether the products described in Sandoz's ANDA Nos. 212068 and 212069 will infringe any valid and enforceable claim of the Patents-in-Suit.

New Drug Application No. 204485

19. On information and belief, Par Sterile Products is the current holder of approved New Drug Application ("NDA") No. 204485 for Vasopressin Injection USP, 200 units/10mL (20 units/mL).

20. NDA No. 204485 was submitted to the U.S. Food and Drug Administration ("FDA") pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which is codified at 21 U.S.C. § 355(b)(2).

21. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act permits the filing of an application for a drug without full reports of investigations to show whether or not such drug is safe for use and whether such drug is effective in use.

22. Pursuant to section 505(b)(2), NDA No. 204485 relied on published literature to support clinical pharmacology, safety, and efficacy for vasopressin. Accordingly, the FDA's March 27, 2014 Summary Review for NDA No. 204485 reports, "On September 25, 2012, the applicant submitted a 505(b)(2) application, relying on published literature alone to support clinical pharmacology, safety and efficacy for vasopressin with a proposed indication for the treatment of vasodilatory shock, including post-cardiotomy shock and septic shock."

23. It was possible for NDA No. 204485 to receive FDA approval based on published literature to support clinical pharmacology, safety and efficacy because of decades of prior use of Pitressin.

24. At least as early as 2012, Pitressin was marketed in the United States by JHP Pharmaceuticals, LLC.

25. JHP Pharmaceuticals, LLC's Pitressin product was also known as vasopressin, injection, USP.

26. The FDA's May 23, 2013 Pediatric and Maternal Health Staff Review for NDA No. 204485 summarizes the history of Pitressin as follows:

> Pitressin (vasopressin, injection, USP) is a synthetic version of vasopressin identical to the natural peptide produced in the posterior pituitary gland. Pitressin is available as an intravenous solution at a concentration of 20 pressor units/mL, and contains the preservative chlorobutanol (a chloroform derivative). This product (manufactured by JHP Pharmaceuticals) is the same product originally marketed by Parke-Davis. Pitressin is a pre-1938 drug product that has never received FDA approval, but has been marketed for almost 100 years.

FDA's Position on Marketed Unapproved Drugs

27. In June 2006, FDA announced a new drug safety initiative to remove unapproved drugs from the market, and issued a final guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide (CPG)" ("the June 2006 Guidance")

28. The June 2006 Guidance includes discussion of two "grandfather clauses" in the Food, Drug and Cosmetic Act. June 2006 Guidance, pp. 10-11. As noted in the June 2006 Guidance, this grandfather clause is codified at 21 U.S.C. § 321(p)(1) and provides that a drug product "shall not be deemed to be a 'new drug' if any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use." 21 U.S.C. § 321(p)(1).

29. The second grandfather clause was enacted in 1962 and provides that for certain pre-1962 drugs, the "conditions of use prescribed, recommended, or suggested in the labeling covered by such application, not be conditioned upon an affirmative finding of the efficacy of such drug." Drug Amendments of 1962, Pub. L. No. 87-781, § 107, 76 Stat. 780, 786 (1962).

30. The June 2006 Guidance stated that the "FDA believes that there are very few drugs on the market that are actually entitled to grandfather status because the drugs currently on the market likely differ from the previous versions in some respect, such as formulation, dosage or strength, dosage form, route of administration, indications, or intended patient population. If a firm claims that its product is grandfathered, it is that firm's burden to prove that assertion." June 2006 Guidance, p. 11.

31. The June 2006 Guidance also stated the FDA's view that the "grandfather clauses . . . have been construed very narrowly by the courts" and "it is not likely that any currently marketed prescription drug product is grandfathered or is otherwise not a *new drug*." June 2006 Guidance, p. 8 (emphasis in original).

32. On September 19, 2011, the FDA issued a revision to its June 2006 "Marketed Unapproved Drugs – Compliance Policy Guide" ("the September 2011 Guidance").

33. The FDA's stated position regarding the grandfather clauses did not change between the June 2006 Guidance and September 2011 Guidance.

34. On information and belief, the FDA's position regarding grandfathered drugs stated in its June 2006 Guidance and/or its September 2011 Guidance contributed to JHP Pharmaceuticals, LLC's decision to submit NDA No. 204485 on September 25, 2012.

FDA's Approval of Par's Vasopressin Product

35. In Civil Action No. 2:16-cv-04544 (D.N.J.), Par admitted that after the submission of NDA No. 204485, Par acquired JHP Pharmaceuticals, LLC, which previously sold

vasopressin injection under the name Pitressin. Par also represented that JHP Pharmaceuticals, LLC was renamed Par Sterile Products, LLC.

36. On April 17, 2014, the FDA issued a first approval letter for NDA No. 204485, which approved the application for vasopressin injection, USP, 20 units per ML.

37. Upon information and belief, the applicant for NDA No. 204485 made no changes to the ingredients or their amounts in the vasopressin injection USP, 20 units per mL that is the subject of NDA No. 204485 between the original submission of NDA No. 204485 on September 25, 2012 and the FDA's approval letter dated April 17, 2014.

38. On December 17, 2016, the FDA issued a second approval letter for NDA No. 204485, which approved the application for vasopressin injection, USP, 200 units per 10 mL pursuant to Par Sterile Products, LLC's Supplemental New Drug Application ("sNDA") submitted March 18, 2016.

39. Plaintiffs/Counterclaim-Defendants sell the drug products under NDA No. 204485 in the United States, including in this district, under the name Vasostrict®.

40. On information and belief, no FDA-approved vasopressin products are currently commercially available in the United States other than Vasostrict®.

41. On information and belief, Vasopressin products that were commercially available prior to the FDA's approval of NDA No. 204485 on April 17, 2014 have been discontinued. For example, the product that JHP Pharmaceuticals, LLC previously sold as Pitressin is no longer commercially available in the United States.

42. In addition, on information and belief, other companies, including Fresenius Kabi USA, LLC and Cardinal Health, marketed vasopressin products in the United States prior to 2015. On information and belief, those products are no longer commercially available in the United States.

PATENTS

43. The earliest filing date for any of the patent applications that issued as the Patents-in-Suit is May 20, 2015.

44. On information and belief, Plaintiffs/Counterclaim-Defendants caused the FDA to list the Patents-in-Suit in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), in connection with NDA No. 204485 for Vasostrict®, 200 units/10 mL

45. On information and belief, Plaintiffs/Counterclaim-Defendants caused the FDA to list the '478, '526, '209, '239, and '785 patents in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), in connection with NDA No. 204485 for Vasostrict®, 20 units/mL.

46. By maintaining the listing of the Patents-in-Suit in the Orange Book for Vasostrict®, 200 units/mL, Plaintiffs/Counterclaim-Defendants have represented that each listed patent covers Vasopressin Injection USP, 200 units/10mL (20 units/mL), and that a claim of patent infringement may reasonably be asserted against any ANDA applicant, including Sandoz, that is not licensed by Plaintiffs/Counterclaim-Defendants and files an ANDA seeking approval to market Vasopressin Injection USP, 200 units/10mL (20 units/mL) prior to the expiration of the Patents-in-Suit.

47. By maintaining the listing of the '478, '526, '209, '239, and '785 patents in the Orange Book for Vasostrict®, 20 units/mL, Plaintiffs/Counterclaim-Defendants have represented that each listed patent covers Vasopressin Injection USP, 20 units/mL, and that a claim of patent infringement may reasonably be asserted against any ANDA applicant, including Sandoz, that is not licensed by Plaintiffs/Counterclaim-Defendants and files an ANDA seeking approval to market Vasopressin Injection USP, 20 units/mL prior to the expiration of the Patents-in-Suit.

SANDOZ'S ANDAs

48. Sandoz filed ANDA Nos. 212068 and 212069 with FDA seeking approval to market its proposed Vasopressin Injection USP, 20units/1mL (20 units/mL) and Vasopressin Injection USP, 200 units/10mL (20 units/mL), respectively.

Sandoz's ANDA No. 212069 (Multi-Dose Vial)

49. In accordance with the requirements of 21 U.S.C. § 355(b)(3)(B) and 21 C.F.R. § 314.52(c), Sandoz sent Plaintiffs/Counterclaim-Defendants a Notice Letter dated August 31, 2018 ("MDV Notice Letter"), stating that Sandoz's ANDA No. 212069 included Paragraph IV Certifications alleging that the Patents-in-Suit are invalid, unenforceable, and will not be infringed by the commercial manufacture, use, offer for sale, or sale of the product described in Sandoz's ANDA No. 212069.

50. Sandoz's MDV Notice Letter included an Offer for Confidential Access ("OCA") to ANDA No. 212069 for the holder of NDA No. 204485 and owner of the Patents-in-Suit so that each could determine whether Sandoz's proposed Vasopressin Injection USP, 200 units/10mL (20 units/mL) infringes any valid claim of the Patents-in-Suit, pursuant to 21 U.S.C. § 355.

51. Pursuant to section 505(j)(2)(B)(iv)(II) of the Federal Food Drug and Cosmetic Act, Sandoz attached to its MDV Notice Letter a detailed statement of the factual and legal bases for Sandoz's Paragraph IV certifications ("MDV Detailed Statement").

52. Sandoz's MDV Notice Letter initiated a 45-day statutory period during which Plaintiffs/Counterclaim-Defendants had the opportunity to file an action for patent infringement.

53. On October 11, 2018, Plaintiffs/Counterclaim-Defendants filed this infringement action under 35 U.S.C. § 271(e)(2), asserting the Patents-in-Suit against Sandoz.

54. Prior to October 11, 2018, Plaintiffs/Counterclaim-Defendants made no effort to obtain information from Sandoz pursuant to the OCA provided with Sandoz's August 31, 2018 MDV Notice Letter.

Sandoz's ANDA No. 212068 (Single-Dose Vial)

55. In accordance with the requirements of 21 U.S.C. § 355(b)(3)(B) and 21 C.F.R. § 314.52(c), Sandoz sent Plaintiffs/Counterclaim-Defendants a Notice Letter dated October 17, 2018 ("SDV Notice Letter"), stating that Sandoz's ANDA No. 212068 included Paragraph IV Certifications, alleging that the '478, '526, '209, '239, and '785 patents are invalid, unenforceable, and will not be infringed by the commercial manufacture, use, offer for sale, or sale of the product described in Sandoz's ANDA No. 212068.

56. Sandoz's SDV Notice Letter included an OCA to ANDA No. 212068 for the holder of NDA No. 204485 and owner of the '478, '526, '209, '239, and '785 patents so that each could determine whether Sandoz's proposed Vasopressin Injection USP, 200 units/10mL (20 units/mL) infringes any valid claim of the '478, '526, '209, '239, and '785 patents pursuant to 21 U.S.C. § 355.

57. Pursuant to section 505(j)(2)(B)(iv)(II) of the Federal Food Drug and Cosmetic Act, Sandoz attached to its SDV Notice Letter a detailed statement of the factual and legal bases for Sandoz's Paragraph IV certifications ("SDV Detailed Statement").

58. Sandoz's SDV Notice Letter initiated a 45-day statutory period during which Plaintiffs/Counterclaim-Defendants had the opportunity to file an action for patent infringement.

59. On November 8, 2018, Plaintiffs/Counterclaim-Defendants filed their First Amended Complaint in the above-captioned suit in which they included allegations that the products that are the subject of ANDA No. 212068 infringe the Patents-in-Suit.

60. Prior to November 8, 2018, Plaintiffs/Counterclaim-Defendants made no effort to obtain information from Sandoz pursuant to the OCA provided with Sandoz's October 17, 2018 SDV Notice Letter.

Case-or-Controversy as to Sandoz's ANDAs

61. As a consequence of Plaintiffs/Counterclaim-Defendants' suit alleging infringement of the '478 patent based on Sandoz's ANDA Nos. 212068 and 212069, Plaintiffs/Counterclaim-Defendants established an actual dispute as to whether the products described in Sandoz's ANDA Nos. 212068 and 212069 infringe the '478 patent and whether the '478 patent is valid. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality exists between Sandoz and Plaintiffs/Counterclaim-Defendants as to whether the claims of the '478 patent are invalid and/or not infringed by the products described in Sandoz's ANDA Nos. 212068 and 212069.

62. As a consequence of Plaintiffs/Counterclaim-Defendants' suit alleging infringement of the '526 patent based on Sandoz's ANDA Nos. 212068 and 212069, Plaintiffs/Counterclaim-Defendants established an actual dispute as to whether the products described in Sandoz's ANDA Nos. 212068 and 212069 infringe the '526 patent and whether the '526 patent is valid. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality exists between Sandoz and Plaintiffs/Counterclaim-Defendants as to whether the claims of the '526 patent are invalid and/or not infringed by the products described in Sandoz's ANDA Nos. 212068 and 212069.

63. As a consequence of Plaintiffs/Counterclaim-Defendants' suit alleging infringement of the '209 patent based on Sandoz's ANDA Nos. 212068 and 212069, Plaintiffs/Counterclaim-Defendants established an actual dispute as to whether the products described in Sandoz's ANDA Nos. 212068 and 212069 infringe the '209 patent and whether the

'209 patent is valid. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality exists between Sandoz and Plaintiffs/Counterclaim-Defendants as to whether the claims of the '209 patent are invalid and/or not infringed by the products described in Sandoz's ANDA Nos. 212068 and 212069.

64. As a consequence of Plaintiffs/Counterclaim-Defendants' suit alleging infringement of the '239 patent based on Sandoz's ANDA Nos. 212068 and 212069, Plaintiffs/Counterclaim-Defendants established an actual dispute as to whether the products described in Sandoz's ANDA Nos. 212068 and 212069 infringe the '239 patent and whether the '239 patent is valid. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality exists between Sandoz and Plaintiffs/Counterclaim-Defendants as to whether the claims of the '239 patent are invalid and/or not infringed by the products described in Sandoz's ANDA Nos. 212068 and 212069.

65. As a consequence of Plaintiffs/Counterclaim-Defendants' suit alleging infringement of the '785 patent based on Sandoz's ANDA Nos. 212068 and 212069, Plaintiffs/Counterclaim-Defendants established an actual dispute as to whether the products described in Sandoz's ANDA Nos. 212068 and 212069 infringe the '785 patent and whether the '785 patent is valid. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality exists between Sandoz and Plaintiffs/Counterclaim-Defendants as to whether the claims of the '785 patent are invalid and/or not infringed by the products described in Sandoz's ANDA Nos. 212068 and 212069.

66. As a consequence of Plaintiffs/Counterclaim-Defendants' suit alleging infringement of the '223 patent based on Sandoz's ANDA Nos. 212068 and 212069, Plaintiffs/Counterclaim-Defendants established an actual dispute as to whether the products described in Sandoz's ANDA Nos. 212068 and 212069 infringe the '223 patent and whether the

'223 patent is valid. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality exists between Sandoz and Plaintiffs/Counterclaim-Defendants as to whether the claims of the '223 patent are invalid and/or not infringed by the products described in Sandoz's ANDA Nos. 212068 and 212069.

FIRST COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '478 PATENT)

67. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

68. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the infringement of the claims of the '478 patent.

69. Sandoz seeks a declaration that no valid or enforceable claim of the '478 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA Nos. 212068 and 212069.

70. In accordance with 21 U.S.C. § 355(j)(2)(B), each of Sandoz's MDV Detailed Statement and SDV Detailed Statement (collectively, "Sandoz's Detailed Statements") included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '478 patent. Sandoz incorporates by reference the

factual and legal bases provided in Sandoz's Detailed Statements and expressly reserves the right to assert additional grounds of non-infringement.

71. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA Nos. 212068 and 212069 would directly and/or indirectly infringe the '478 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA Nos. 212068 and 212069 within the United States have not infringed and will not infringe, directly and/or indirectly, the '478 patent.

72. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA Nos. 212068 and 212069 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '478 patent.

SECOND COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '478 PATENT)

73. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

74. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '478 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the invalidity of the claims of the '478 patent.

75. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statements each included a detailed statement of the factual and legal bases for why the claims of the '478 patent are invalid. Sandoz incorporates by reference the factual and legal bases provided in Sandoz's Detailed Statements.

76. For example, the claims of the '478 patent are invalid for failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including that the claimed subject matter is invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in Sandoz's Detailed Statements, each alone or in combination with one or more others and the knowledge of a person of ordinary skill in the art, including (but not limited to): M.L. Buck, *Low-dose Vasopressin Infusions for Vasodilatory Shock*, PEDIATRIC PHARMACOTHERAPY, Sept. 2004 ("Buck"), Fresenius Kabi USA, LLC, *Vasopressin Injection USP* (2013) ("Fresenius"), and K. Adamsons, Jr. et al., *The Stability of Natural and Synthetic Neurophysical Hormones* in Vitro, 63 ENDOCRINOLOGY 679 (1958) ("Adamsons"). Sandoz expressly reserves the right to assert that the claims of the '478 patent are invalid based on additional or alternative grounds and anticipated and/or obvious in view of additional references alone or in combination with one or more others and the knowledge of a person of ordinary skill in the art as of the relevant time.

77. In addition, as set forth in Sandoz's Detailed Statements, the claims of the '478 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 112, including the written description requirement, enablement requirement, and the definiteness requirement.

78. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '478 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '478 patent and the claims thereof are invalid for

failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

79. Sandoz is entitled to a declaration that the claims of the '478 patent are invalid.

THIRD COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '526 PATENT)

80. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

81. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the infringement of the claims of the '526 patent.

82. Sandoz seeks a declaration that no valid or enforceable claim of the '526 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA Nos. 212068 and 212069.

83. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statements each included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '526 patent. Sandoz incorporates by reference these

factual and legal bases provided in Sandoz's Detailed Statements and expressly reserves the right to assert additional grounds of non-infringement.

84. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA Nos. 212068 and 212069 would directly and/or indirectly infringe the '526 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA Nos. 212068 and 212069 within the United States have not infringed and will not infringe, directly and/or indirectly, the '526 patent.

85. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA Nos. 212068 and 212069 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '526 patent.

FOURTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '526 PATENT)

86. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

87. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '526 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the invalidity of the claims of the '526 patent.

88. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statements each included a detailed statement of the factual and legal bases for why the claims of the '526 patent are invalid. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's Detailed Statements.

89. For example, the claims of the '526 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '526 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in Sandoz's Detailed Statements, alone or in combination with one another and/or the knowledge of a person of skill in the art, including (but not limited to): Buck, Fresenius, and Adamsons. Sandoz expressly reserves the right to assert that the claims of the '526 patent are invalid based on additional or alternative grounds and anticipated or obvious in view of additional references alone or in combination with one or more others and the knowledge of a person of ordinary skill in the art.

90. In addition, as set forth in Sandoz's Detailed Statement, the claims of the '526 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 112, including the written description requirement, enablement requirement, and the definiteness requirement.

91. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '526 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '526 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-

type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

92. Sandoz is entitled to a declaration that the claims of the '526 patent are invalid.

FIFTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '209 PATENT)

93. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the infringement of the claims of the '209 patent.

95. Sandoz seeks a declaration that no valid or enforceable claim of the '209 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA Nos. 212068 and 212069.

96. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statements each included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '209 patent. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's Detailed Statements and expressly reserves the right to assert additional grounds of non-infringement.

97. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA Nos. 212068 and 212069 would directly and/or indirectly infringe the '209 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA Nos. 212068 and 212069 within the United States have not infringed and will not infringe, directly and/or indirectly, the '209 patent.

98. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA Nos. 212068 and 212069 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '209 patent.

SIXTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '209 PATENT)

99. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

100. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '209 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the invalidity of the claims of the '209 patent.

101. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statements each included a detailed statement of the factual and legal bases for why the claims of the '209 patent

are invalid. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's Detailed Statements.

102. For example, the claims of the '209 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '209 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in Sandoz's Detailed Statements, alone or in combination with one another and/or the knowledge of a person of skill in the art, including (but not limited to): Buck, Fresenius, and Adamsons. Sandoz expressly reserves the right to assert that the claims of the '209 patent are invalid based on additional or alternative grounds and anticipated or obvious in view of additional references alone or in combination with one or more others and the knowledge of a person of ordinary skill in the art.

103. In addition, as set forth in Sandoz's Detailed Statement, the claims of the '209 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 112, including the written description requirement, enablement requirement, and the definiteness requirement.

104. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '209 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '209 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

105. Sandoz is entitled to a declaration that the claims of the '209 patent are invalid.

SEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '239 PATENT)

106. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

107. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the infringement of the claims of the '239 patent.

108. Sandoz seeks a declaration that no valid or enforceable claim of the '239 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA Nos. 212068 and 212069.

109. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statements each included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '239 patent. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's Detailed Statements and expressly reserves the right to assert additional grounds of non-infringement.

110. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA Nos. 212068 and 212069 would directly and/or indirectly infringe the '239 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA

Nos. 212068 and 212069 within the United States have not infringed and will not infringe, directly and/or indirectly, the '239 patent.

111. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA Nos. 212068 and 212069 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '239 patent.

EIGHTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '239 PATENT)

112. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

113. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '239 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the invalidity of the claims of the '239 patent.

114. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statements each included a detailed statement of the factual and legal bases for why the claims of the '239 patent are invalid. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's Detailed Statements.

115. For example, the claims of the '239 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '239 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least

the references cited in Sandoz's Detailed Statement, alone or in combination with one another and/or the knowledge of a person of skill in the art, including (but not limited to): Buck, Fresenius, and Adamsons. Sandoz expressly reserves the right to assert that the claims of the '239 patent are invalid based on additional or alternative grounds and anticipated or obvious in view of additional references alone or in combination with one or more others and the knowledge of a person of ordinary skill in the art.

116. In addition, as set forth in Sandoz's Detailed Statements, the claims of the '239 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 112, including the written description requirement, enablement requirement, and the definiteness requirement.

117. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '239 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '239 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

118. Sandoz is entitled to a declaration that the claims of the '239 patent are invalid.

NINTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '785 PATENT)

119. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

120. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual,

substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the infringement of the claims of the '785 patent.

121. Sandoz seeks a declaration that no valid or enforceable claim of the '785 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of products described in Sandoz's ANDA Nos. 212068 and 212069.

122. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statement included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '785 patent. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's Detailed Statement and expressly reserves the right to assert additional grounds of non-infringement.

123. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA Nos. 212068 and 212069 would directly and/or indirectly infringe the '785 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA Nos. 212068 and 212069 within the United States have not infringed and will not infringe, directly and/or indirectly, the '785 patent.

124. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA Nos. 212068 and 212069 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '785 patent.

TENTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '785 PATENT)

125. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

126. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '785 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the invalidity of the claims of the '785 patent.

127. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's Detailed Statements each included a detailed statement of the factual and legal bases for why the claims of the '785 patent are invalid. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's Detailed Statements.

128. For example, the claims of the '785 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '785 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in Sandoz's Detailed Statements, alone or in combination with one another and/or the knowledge of a person of skill in the art, including (but not limited to): Buck, Fresenius, and Adamsons. Sandoz expressly reserves the right to assert that the claims of the '785 patent are invalid based on additional or alternative grounds and anticipated or obvious in view of additional references alone or in combination with one or more others and the knowledge of a person of ordinary skill in the art.

129. In addition, as set forth in Sandoz's Detailed Statements, the claims of the '785 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 112, including the written description requirement, enablement requirement, and the definiteness requirement.

130. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '785 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '785 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

131. Sandoz is entitled to a declaration that the claims of the '785 patent are invalid.

ELEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '223 PATENT)

132. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

133. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the infringement of the claims of the '223 patent.

134. Sandoz seeks a declaration that no valid or enforceable claim of the '223 patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use,

importation, sale, or offer for sale of products described in Sandoz's ANDA Nos. 212068 and 212069.

135. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's MDV Detailed Statement included a detailed statement of the factual and legal bases for why Sandoz has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '223 patent. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's MDV Detailed Statement and expressly reserves the right to assert additional grounds of non-infringement.

136. Because Plaintiffs/Counterclaim-Defendants maintain that the commercial manufacture, use, offer for sale, or sale of the products described in ANDA Nos. 212068 and 212069 would directly and/or indirectly infringe the '223 patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of the products described in Sandoz's ANDA Nos. 212068 and 212069 within the United States have not infringed and will not infringe, directly and/or indirectly, the '223 patent.

137. Sandoz is entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of products described in ANDA Nos. 212068 and 212069 have not infringed and will not infringe, directly and/or indirectly, any valid or enforceable claim of the '223 patent.

TWELFTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '223 PATENT)

138. Sandoz realleges and incorporates by reference each of the preceding paragraphs as if fully set forth herein.

139. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a

declaration that the claims of the '223 patent are invalid. A case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Plaintiffs/Counterclaim-Defendants and Sandoz concerning the invalidity of the claims of the '223 patent.

140. In accordance with 21 U.S.C. § 355(j)(2)(B), Sandoz's MDV Detailed Statement included a detailed statement of the factual and legal bases for why the claims of the '223 patent are invalid. Sandoz incorporates by reference these factual and legal bases provided in Sandoz's MDV Detailed Statement.

141. For example, the claims of the '223 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 103. By way of non-limiting example, the claims of the '223 patent are invalid as obvious pursuant to 35 U.S.C. § 103 in view of at least the references cited in Sandoz's MDV Detailed Statement, alone or in combination with one another and/or the knowledge of a person of skill in the art, including (but not limited to): Buck, Fresenius, and Adamsons. Sandoz expressly reserves the right to assert that the claims of the '223 patent are invalid based on additional or alternative grounds and anticipated or obvious in view of additional references alone or in combination with one or more others and the knowledge of a person of ordinary skill in the art.

142. In addition, as set forth in Sandoz's MDV Detailed Statement, the claims of the '223 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 112, including the written description requirement, enablement requirement, and the definiteness requirement.

143. Because Plaintiffs/Counterclaim-Defendants maintain and Sandoz denies that the '223 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '223 patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

144. Sandoz is entitled to a declaration that the claims of the '223 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim-Plaintiff Sandoz respectfully requests that this Court enter a Judgment and Order:

A. dismissing the First Amended Complaint, and the claims for relief contained therein, with prejudice;

B. declaring that Sandoz and the products described in ANDA Nos. 212068 and 212069 have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '478 patent;

C. declaring that the claims of the '478 patent are invalid;

D. declaring that Sandoz and the products described in ANDA Nos. 212068 and 212069 have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '526 patent;

E. declaring that the claims of the '526 patent are invalid;

F. declaring that Sandoz and the products described in ANDA Nos. 212068 and 212069 have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '209 patent;

G. declaring that the claims of the '209 patent are invalid;

H. declaring that Sandoz and the products described in ANDA Nos. 212068 and 212069 have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '239 patent;

I. declaring that the claims of the '239 patent are invalid;

J. declaring that Sandoz and the products described in ANDA Nos. 212068 and 212069 have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '785 patent;

K. declaring that the claims of the '785 patent are invalid;

L. declaring that Sandoz and the products described in ANDA Nos. 212068 and 212069 have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '223 patent;

M. declaring that the claims of the '223 patent are invalid;

N. declaring this an exceptional case under 35 U.S.C. § 285 and awarding Sandoz attorney fees, costs, and expenses; and

O. granting Sandoz such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Sandoz Inc. hereby demands a jury trial on all issues so triable.

Dated: November 20, 2018

Respectfully submitted,

By: /s/Eric I. Abraham

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, Defendant, through its counsel, certifies that the matter in controversy is not the subject of another action pending in any court or of any pending arbitration or administrative proceeding. However, Defendant notes that one or more of the Patents-in-Suit are the subject of other actions pending in this and other federal districts, including, *Par Pharmaceutical, Inc. et al v. QuVa Pharma, Inc. et al*, CA No. 3:17-cv-06115 (D.N.J.), *Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc.*, CA No. 1:18-cv-00823 (D. Del.), and *Athenex Pharma Solutions, LLC et al v. Par Pharmaceutical, Inc. et al*, CA No. 1:18-cv-00896 (W.D.N.Y.).

Dated: November 20, 2018

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, Defendant, through its counsel, certifies that it seeks declaratory relief, and therefore the above captioned matter is not appropriate for compulsory arbitration.

Dated: November 20, 2018

Respectfully submitted,

By: /s/Eric I. Abraham

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Attorneys for Defendant Sandoz Inc.

CERTIFICATION OF SERVICE

I hereby certify that on November 20, 2018, the foregoing document was filed via CM/ECF with the Clerk of the Court and was thereby served on all counsel of record in this matter.

Dated: November 20, 2018

Respectfully submitted,

By: __/s/Eric I. Abraham_____
Eric I. Abraham